Notice of Allowability	Application No.	Applicant(s)	
	10/695,265	KADDURAH-DAOUK ET AL.	
	Examiner	Art Unit	
	Heather G. Calamita, Ph.D.	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *the reply filed December 12, 2006*.

2. ☒ The allowed claim(s) is/are *95,140,141,143-148 and 150-170*.

3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

hgc

JEFFREY FREDMAN
PRIMARY EXAMINER
3/1/07

EXAMINER'S AMENDMENT

1. Authorization for this examiner's amendment was given in a telephone interview with Cynthia Soroos on March 1, 2007.

The application has been amended as follows:

Cancel without prejudice claims 91, 96, 142 and 149.

IN THE CLAIMS:

95. The method of claim 143, wherein said subject is a human.

140. The method of claim 143, wherein said small molecule profiles are obtained from said subject's tissue or biological fluids.

141. The method of claim 143, wherein said small molecule profiles are obtained using one or more of the following: HPLC, TLC, electrochemical analysis, mass spectroscopy, refractive index spectroscopy (RI), Ultra-Violet spectroscopy (UV), fluorescent analysis, gas chromatography (GC), radiochemical analysis, Near-InfraRed spectroscopy (Near-IR), Nuclear Magnetic Resonance spectroscopy (NMR), and Light Scattering analysis (LS).

143. A method for metabolomically identifying small molecules indicative of amyotrophic lateral sclerosis, comprising:

obtaining a small molecule profile from a subject suffering from amyotrophic lateral sclerosis; and

comparing the small molecule profile from the subject to a standard small molecule profile, thereby identifying small molecules indicative of amyotrophic lateral sclerosis, wherein said small molecule profile is obtained using one or more techniques which detect 50% or more of the small molecules in said sample.

144. A method for metabolomically identifying small molecules indicative of Alzheimer's disease, comprising:

obtaining a small molecule profile from a subject suffering from Alzheimer's disease; and

comparing the small molecule profile from the subject to a standard small molecule profile, thereby identifying small molecules indicative of Alzheimer's disease, wherein said small molecule

profile is obtained using one or more techniques which detect 50% or more of the small molecules in said sample.

145. A method for metabolomically identifying small molecules indicative of Huntington's disease, comprising:

obtaining a small molecule profile from a subject suffering from Huntington's disease; and

comparing the small molecule profile from the subject to a standard small molecule profile, thereby identifying small molecules indicative of Huntington's disease, wherein said small molecule profile is obtained using one or more techniques which detect 50% or more of the small molecules in said sample.

146. A method for metabolomically identifying small molecules indicative of Parkinson's disease, comprising:

obtaining a small molecule profile from a subject suffering from Parkinson's disease; and

comparing the small molecule profile from the subject to a standard small molecule profile, thereby identifying small molecules indicative of Parkinson's disease, wherein said small molecule profile is obtained using one or more techniques which detect 50% or more of the small molecules in said sample.

147. A method for metabolomically identifying small molecules indicative of depression, comprising:

obtaining a small molecule profile from a subject suffering from depression; and

comparing the small molecule profile from the subject to a standard small molecule profile, thereby identifying small molecules indicative of depression, wherein said small molecule profile is obtained using one or more techniques which detect 50% or more of the small molecules in said sample.

148. A method for metabolomically identifying small molecules indicative of schizophrenia, comprising:

obtaining a small molecule profile from a subject suffering from schizophrenia; and

comparing the small molecule profile from the subject to a standard small molecule profile, thereby identifying small molecules indicative of schizophrenia, wherein said small molecule profile is obtained using one or more techniques which detect 50% or more of the small molecules in said sample.

150. The method of claim 143, wherein said small molecule profiles are obtained from said subject's blood, spinal fluid, serum, cells, cellular organelles, urine, interstitial fluid, or saliva.

151. The method of claim 144, wherein said subject is a human.

152. The method of claim 144, wherein said small molecule profiles are obtained from said subject's tissue or biological fluids.

153. The method of claim 144, wherein said small molecule profiles are obtained from said subject's blood, spinal fluid, serum, cells, cellular organelles, urine, interstitial fluid, or saliva.

154. The method of claim 144, wherein said small molecule profiles are obtained using one or more of the following: HPLC, TLC, electrochemical analysis, mass spectroscopy, refractive index spectroscopy (RI), Ultra-Violet spectroscopy (UV), fluorescent analysis, radiochemical analysis, Near-InfraRed spectroscopy (Near-IR), Nuclear Magnetic Resonance spectroscopy (NMR), gas chromatography (GC) and Light Scattering analysis (LS).

155. The method of claim 145, wherein said subject is a human.

156. The method of claim 145, wherein said small molecule profiles are obtained from said subject's tissue or biological fluids.

157. The method of claim 145, wherein said small molecule profiles are obtained from said subject's blood, spinal fluid, serum, cells, cellular organelles, urine, interstitial fluid, or saliva.

158. The method of claim 145, wherein said small molecule profiles are obtained using one or more of the following: HPLC, TLC, electrochemical analysis, mass spectroscopy, refractive index spectroscopy (RI), Ultra-Violet spectroscopy (UV), fluorescent analysis, radiochemical analysis, Near-InfraRed spectroscopy (Near-IR), Nuclear Magnetic Resonance spectroscopy (NMR), gas chromatography (GC), and Light Scattering analysis (LS).

159. The method of claim 146, wherein said subject is a human.

160. The method of claim 146, wherein said small molecule profiles are obtained from said subject's tissue or biological fluids.

161. The method of claim 146, wherein said small molecule profiles are obtained from said subject's blood, spinal fluid, serum, cells, cellular organelles, urine, interstitial fluid, or saliva.

162. The method of claim 146, wherein said small molecule profiles are obtained using one or more of the following: HPLC, TLC, electrochemical analysis, mass spectroscopy, refractive index spectroscopy (RI), Ultra-Violet spectroscopy (UV), fluorescent analysis, radiochemical analysis, Near-InfraRed spectroscopy (Near-IR), Nuclear Magnetic Resonance spectroscopy (NMR), gas chromatography (GC), and Light Scattering analysis (LS).

163. The method of claim 147, wherein said subject is a human.

164. The method of claim 147, wherein said small molecule profiles are obtained from said subject's tissue or biological fluids.

165. The method of claim 147, wherein said small molecule profiles are obtained from said subject's blood, spinal fluid, serum, cells, cellular organelles, urine, interstitial fluid, or saliva.

166. The method of claim 147, wherein said small molecule profiles are obtained using one or more of the following: HPLC, TLC, electrochemical analysis, mass spectroscopy, refractive index spectroscopy (RI), Ultra-Violet spectroscopy (UV), fluorescent analysis, radiochemical analysis, Near-InfraRed spectroscopy (Near-IR), Nuclear Magnetic Resonance spectroscopy (NMR), gas chromatography (GC), and Light Scattering analysis (LS).

167. The method of claim 148, wherein said subject is a human.

168. The method of claim 148, wherein said small molecule profiles are obtained from said subject's tissue or biological fluids.

169. The method of claim 148, wherein said small molecule profiles are obtained from said subject's blood, spinal fluid, serum, cells, cellular organelles, urine, interstitial fluid, or saliva.

170. The method of claim 148, wherein said small molecule profiles are obtained using one or more of the following: HPLC, TLC, electrochemical analysis, mass spectroscopy, refractive index spectroscopy (RI), Ultra-Violet spectroscopy (UV), fluorescent analysis, radiochemical analysis, Near-InfraRed

spectroscopy (Near-IR), Nuclear Magnetic Resonance spectroscopy (NMR), gas chromatography (GC), and Light Scattering analysis (LS).

REASONS FOR ALLOWANCE

2. The following is an examiner's statement of reasons for allowance: Applicants amendments and declaration filed December 12, 2007 places the claims in condition for allowance. The closest prior art is Niebroj-Dobosz et al., Siman et al., and Kaser et al. These references do not teach detecting 50% or more of the small molecules in a sample. The claims are therefore novel and unobvious over the prior art. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Correspondence

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Heather G. Calamita whose telephone number is 571.272.2876 and whose e-mail address is heather.calamita@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route. The examiner can normally be reached on Monday through Thursday, 7:00 AM to 5:30 PM.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at 571.272.0782.

Papers related to this application may be faxed to Group 1637 via the PTO Fax Center using the fax number 571.273.8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to 571.272.0547.

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3/1/07